



Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED

November 25, 1996

cc: HFI-35/FOI Staf
DWA

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Refer to MIN 96 - 14

Liza H. Vogt
Owner
Tianna Farms Kitchen
Box 968, Pine Street
Walker, Minnesota 56484

Dear Ms. Vogt:

During an inspection of your firm on October 21, 1996, Investigator Alice J. Krivitsky collected labels and samples of your products. The inspection revealed serious deviations from Title 21, Code of Federal Regulations, Parts 108 and 114 (21 CFR 108 and 114). A copy of 21 CFR 100-169 was provided by the investigator to Ms. Brown during the inspection. By virtue of these deficiencies, the products processed at your facility are adulterated within the meaning of Section 402(a)(3) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

Specifically, the investigator found that:

1. The manufacturing processes used do not result in temperatures and pH values that meet the critical factors of the filed processes [21 CFR 108.25(c)(3)].
2. The 1995 processes have not been reviewed by a process authority [21 CFR 114.83].

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3. Batches processed with deviations from the established processes were not set aside for evaluation by a process authority, or for reprocessing or destruction [21 CFR 114.89].
4. Departures from the scheduled processes have not been recorded and made the subject of a separate file [21 CFR 114.100(c)].
5. Container size is not always documented on the process record [21 CFR 114.100(b)].
6. Plans for recall of products have not been prepared and maintained [21 CFR 108.25(e)].

It should be noted the investigator's record review observation applies only to low-acid foods (finished pH greater than 4.6) such as your vegetable soup product. The regulations covering this product, should you continue its production, are in Part 113 of the CFR.

Analytical results of the three samples collected are as follows:

- (1) Three jars of the Kosher Dill Pickles with pH values of 4.25, 4.16 and 4.16. The maximum pH specified in the filed process is 3.5.
- (2) Three jars of Dilly Beans with pH values of 3.79, 3.84 and 3.78 (exceeding filed process maximum of 2.8) and net weights of 15.14 14.90 and 14.84 oz. (average 93.5% of declared).
- (3) Three jars of Green Pepper Jelly with acceptable pH values of 3.44, 3.42 and 3.42 (do not exceed the filed process maximum of 3.6).

The labels do not have the nutrition labeling required by the Nutrition Labeling and Education Act of 1990 (NLEA). If you believe you are entitled to an exemption under the regulations for low-volume foods or small businesses, you must file a notice of eligibility and provide the information necessary to verify your exempt status. A model small business food labeling exemption notice and instructions for completion are enclosed. A copy of the regulations requiring food

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You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Within 15 days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days state the reason for the delay and the time within which the correction will be completed. Your response should be sent to the attention of Judy E. Heisick, Compliance Officer, at the address indicated on the letterhead.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John Feldman", with a large, stylized initial "J" and "F".

John Feldman
Director
Minneapolis District

JEH/ccl

Enclosure: NLEA Exemption Notice and Guide

xc: Kathy G. Brown
Kitchen Supervisor
Tianna Farms Kitchen
Box 968, Pine Street
Walker, MN 56484